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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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03/16/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/562,113	Applicant(s) GUO ET AL.	
	Examiner JAGADISHWAR R. SAMALA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/20/2007</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

- Claims 21-45 have been cancelled.
- Claims 1-20 are pending in the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/20/2007 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “less than about” in claims 5-8 is a relative term that renders the claims indefinite. The term “at least about” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term is unclear as to what the endpoints of the ranges/limitations are for the claim.

The term “at least about” in claims 9-10 is a relative term that renders the claims indefinite. The term “at least about” is not defined by the claim, the specification does not

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provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term is unclear as to what the endpoints of the ranges/limitations are for the claim.

See *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), where the court held that claims reciting “at least about” were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term “about.” (See MPEP 2173.05 [R-5] “Relative Terminology”).

This ruling would apply to “less than approximately” or “greater than approximately”.

Claim Objections

Claim 20 is objected to because of the following informalities: In the claim “ammomium acryloyldimethlaurate-beheneth-25 methacrylate copolymer” there is spelling mistake. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al (US 5,681,849), in view of Klug et al (US 6,884,409), Kearns et al (US 2004/0234628) and Krauser (US 2005/0032900).

Applicant claims are drawn to a topical composition comprising aqueous phase, at least one alcohol, a polymeric thickening agent, skin penetration enhancing agent, an emulsifying agent and an active agent.

Richter teaches a topical composition such as gels or lotions comprising water, about 60 to 71%, a lower C₁-C₄ alcohol preferably ethanol from about 5% to about 90% (col. 3 lines 63+), suitable solubilizing agents such as Cremophor RH 40 (polyethoxy-40-hydrogenated castor oil, reads on emulsifying agent) (col. 3 lines 47-48 and col. 6 lines 40-41), polymeric thickeners such as carbomers, polyacrylic acid derivatives (col. 4 lines 60-63), an active agent such as terbinafine (abstract). Additional disclosure includes that the composition has improved cosmetic properties, such as facilitated spreading on the skin and absence of conventional emulsifiers, they also possess improved pharmacological properties, in particular better tolerability when applied to infected and often inflamed skin. A further advantage of the composition is that the appearance and consistency of the final formulation may be freely regulated by varying the proportion of thickening agent in the formulation (col. 5 lines 4-14).

Richter fails to teach particularly thickener ammonium acryloyldimethyl laurate-beheneth-25 methacrylate crosspolymer, Germaben II-E and skin penetration enhancing compound 2-n-nonyl-1, 3-dioxolane.

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Klug teaches a composition comprising active agent such as anesthetics, antibiotics, antimicrobial agent in amounts of 0.01 to 10% by weight (col. 2 lines 45-48), an alcohols such as ethanol, propanol in amounts of 20 to 60% by weight (col. 3 lines 30-33), emulsifiers such as castor oil, triglycerides of caprylic/capric acids (col. 4 lines 19-26), polymer thickeners such as, Aristoflex HMB (ammonium acryloyldimethyl taurate-behenate-25 methacrylate copolymer, a functional equivalent of ammonium acryloyldimethyl laurate-beheneth-25 methacrylate crosspolymer, col. 5 lines 24-34 and col. 7 and 8). The compositions can be supplied in various forms such as gels, lotions, creams, and powders and comprise gelling agents (polyamides and polyacrylamides or mixtures thereof) which, dissolved in the liquid phase, form a network structure and thus solidify the liquid phase.

Kearns teaches a topical composition comprising active agent, emulsifier, carrier oils, surfactant and preservative such as Germaben II-E (abstract and 0028). The composition can be prepared in a variety of topical compositions including creams, ointment and lotions (0031).

Krauser teaches neutral cream formulations comprising an emulsifying and therapeutically effective amount of ibuprofen (abstract). The formulation contains liquid type skin penetration enhancing compound, such as C₇ to C₁₄-hydrocarbonyl substituted 1, 3-dioxolane, 1, 3-dioxane or acetal, especially 2-n-nonyl-1, 3-dioxolane (0007 and 0029). The amounts of enhancer compounds to provide the desired delivery rate for the active compound in the range of from about 1 to 20% (0101). The emulsified composition further comprises thickening agents such as acrylic acid polymers,

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carbopol 974B, carbopol 980, the amount of the thickening agent is not particularly critical and can be selected to provide the desired product consistency or viscosity to allow for easy application to the skin and ranges to about 5% (0117 and 0118).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate polymeric thickener such as ammonium acryloyldimethyl laurate-beheneth-25 methacrylate crosspolymer, into Richter's composition. The person of ordinary skill in the art would have been motivated to make those modifications because by incorporating the polymeric thickeners into the composition, the degree of viscosity may be controlled by the use of suitable thickening agent in desired amounts, can increase the rheological properties, and would have expected success because Aristoflex HMB (ammonium acryloyldimethyl taurate-behenate-25 methacrylate copolymer, a functional equivalent of ammonium acryloyldimethyl laurate-beheneth-25 methacrylate crosspolymer or polymeric thickeners such as carbomers, polyacrylic acid derivatives) used in Richter's composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate Germaben II-E into Richter's composition. The person of ordinary skill in the art would have been motivated to make those modifications because incorporation of preservative such as Germaben II-E into composition would increase the stability of the active ingredient and make the composition more potent, and reasonably would have expected success because it is well known in the art that composition comprising preservative will increase the shelf life

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of the composition and further prevents the growth of antimicrobials that the active ingredients might not be able to prevent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate skin penetration enhancing compound 2-n-nonyl-1,3-dioxolane into Richter's composition. The person of ordinary skill in the art would have been motivated to make those modifications because Krauser teaches that incorporation of skin penetration enhancer compounds provide the desired delivery rate of the active compound (i.e., the penetration of the active ingredient through the skin is enhanced to an acceptable level), and would have had a reasonable expectation of success because Krauser teaches that with an oily skin penetration enhancer, that even before the addition of a conventional emulsifying agent, the combination of ibuprofen, 2-n-nonyl-1,3-dioxolane and water, in the presence of a small amount of a base, formed a homogeneous composition, thereby providing an optimal flux rate and 24 hour payload of the active ingredient (0007 and 0101).

The amount of polymeric thickening agent in a pharmaceutical composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of polymeric thickening agent in order to achieve the desired results, such as topical compositions where, the degree of viscosity may be controlled by the use of suitable thickening agent in desired amounts, and also to increase the

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rheological properties. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of polymeric thickening agent would have been obvious at the time of Applicant's invention.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Jake M. Vu/
Primary Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
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